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The Proposed Patients' Rights Directive and the Reform of (Cross-Border) Healthcare in the European Union

Wolf SAUTER*

The European Commission's (hereinafter 'Commission's') proposal for a directive on patients' rights in cross-border healthcare is not primarily a codification of the case law; while leaving out guarantees developed by the Court (notably based on 'undue delay'), it also adds new elements of liberalization and harmonization. The proposal's liberalization dimension involves eliminating prior authorization requirements for reimbursement of cross-border treatment in most cases. By way of harmonization, the proposal introduces new rights to accountability and transparency, which apply not just to mobile patients but also to all patients in each Member State. Jointly, this will generate pressure for further change, not just in relation to the cross-border provision of services but also more broadly across the healthcare sector.

1. INTRODUCTION

In July 2008, the Commission proposed a Draft Directive on the Application of Patients' Rights in Cross-Border Healthcare (hereinafter 'Proposed Patients' Rights Directive') in the context of the renewed social agenda of the European Union (EU).¹ This was a daring move because, so far, the Member States generally regard healthcare reform not just as one of the most intractable political problems but also as an issue that should remain the preserve of national politics. Moreover:

- To bolster their control over healthcare provision, the Member States have limited the competence of the EU to take the initiative on healthcare issues by adding an explicit treaty provision to this effect, Article 152 EC.
- The Court of Justice has time and again recognized the right of the Member States to determine unilaterally (i.e., at national level) the scope of and eligibility for social security benefits.²

* Tilburg Centre of Law and Economics (TILEC) and Dutch Healthcare Authority (NZa). All opinions expressed here are personal. I am grateful to Leigh Hancher and Damian Chalmers for comments on an earlier version of this text.

¹ Commission Communication of 2 Jul. 2008, Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare presented by the Commission, COM (2008) 414 final.

² Cf., e.g., Case No. 238/82 *Duphar BV et al. v. The Netherlands* [1984] ECR 523, para. 16; Joined Case Nos C-159/91 and C-160/91 *Christian Poucet v. Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon* [1993] ECR I-637, para. 6; Case No. C-70/95 *Sodemare S.A., Anni Azzurri Holding SpA and Anni Azzurri Rezzato Srl v. Regione Lombardia* (hereinafter 'Sodemare') [1997] ECR I-3395, para. 27; and Case No. C-158/96 *Raymond Kohll v. Union des caisses de maladie* (hereinafter 'Kohll') [1998] ECR I-1931, para. 17.

- An earlier attempt by the Commission to codify the more activist patient mobility case law of the Court in the context of the Services Directive in 2004 backfired badly. It ended up having to withdraw the relevant provisions in order to save the directive itself.³

Yet arguably, the Commission's July 2008 initiative was not just risky but also necessary. Across the EU, national healthcare systems vary widely in terms of key variables such as accessibility, quality, and affordability and in the role played by the public, respectively, the private sector. Nevertheless, all these healthcare systems are based upon notions of national solidarity that are increasingly under pressure. Rising healthcare expenditures due to aging populations, ongoing medical innovation, and rising expectations are almost universally triggering cost controls involving various forms of rationing of treatment, such as waiting lists. Change in the healthcare sector – for example, moving from centralized command and control with supply-driven systems to decentralized demand-led provision and promoting efficiency by means of market-based incentives or new entry – is resisted by strong vested interests. Moreover, access to healthcare is an emotive issue. The resulting inability to reform the status quo frequently leads to the emergence of parallel systems that are outside the scope of social security and based on the ability to pay. Thus, rejecting change erodes not only accessibility, quality, and affordability but solidarity as well.

It is against this unpromising background that, from *Raymond Kohll v. Union des caisses de maladie* (hereinafter 'Kohll') to *The Queen, ex parte Yvonne Watts v. Bedford Primary Care Trust and Secretary of State for Health* (hereinafter 'Watts'),⁴ the European Court of Justice (ECJ) has developed a remarkable strand of case law over the past decade in which it applied the freedom to provide services to healthcare (alongside, in a number of cases, Regulation 1408/71,⁵ the applicable social security legislation based on the free

³ European Commission, Proposal for a Directive of the European Parliament and of the Council on services in the internal market 2004/0001 (COD) [SEC(2004) 21] COM (2004) 2 final/3, 5 Mar. 2004, especially Art. 23 thereof. Cf. Directive 2006/123/EC of the European Parliament and of the Council of 12 Dec. 2006 on services in the internal market, OJ 2006 L376/36 (Services Directive), Art. 2, para. 2, subpara. f, and the Preamble, Recital 23.

⁴ Case No. C-158/96 *Kohll* supra n. 2; Case No. C-120/95 *Nicolas Decker v. Caisse de maladie des employés privés* (hereinafter 'Decker') [1998] ECR I-1831; Case No. C-368/98 *Abdon Vanbraeckel et al. v. Alliance nationale des mutualités chrétiennes* [2001] ECR I-5363; Case No. C-157/99 *B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ* (hereinafter 'Geraets-Smits') and *H.T.M. Peerbooms v. Stichting CZ Groep Zorgverzekeringen* (hereinafter 'Peerbooms') [2001] ECR I-5473; Case No. C-385/99 *V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA* (hereinafter 'Müller-Fauré') and *E.E.M. van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen* [2003] ECR I-4509; Case No. C-56/01 *Patricia Inizan v. Caisse primaire d'assurance maladie des Hauts-de-Seine* (hereinafter 'Inizan') [2003] ECR I-12403; Case No. C-8/02 *Ludwig Leichtle v. Bundesanstalt für Arbeit* [2004] ECR I-2641; Case No. C-193/03 *Betriebskrankenkasse der Robert Bosch GmbH v. Germany* [2004] ECR I-991; Case No. C-145/03 *Heirs of Annette Keller v. Instituto Nacional de la Seguridad Social (INSS) and Instituto Nacional de Gestión Sanitaria (Ingesa)* [2005] ECR I-2529; Case No. C-372/04 *The Queen, ex parte Yvonne Watts v. Bedford Primary Care Trust and Secretary of State for Health* (hereinafter 'Watts') [2006] ECR I-4325; Case No. C-466/04 *Manuel Aceveda Herrera v. Servicio Cántabro de Salud* [2006] ECR I-5341; Case No. C-444/05 *Aikaterini Stamatiaki v. NPDD Organismos Asfaliseos Eleftheron Epangelmaton* [2007] ECR I-3185. For a detailed discussion of these cases and further references, see W. Sauter, 'TILEC Discussion Paper No. 2008-034', <<http://ssrn.com/abstract=1277110>>.

⁵ Regulation (EEC) No. 1408/71 of the Council of 14 Jun. 1971 on the application of social security schemes to employed persons and their families moving within the Community (OJ 1971 L149/2), last amended by Regulation (EC) No. 1992/2006 of the European Parliament and of the Council of 18 Dec. 2006, OJ 2006 L392/1 (hereinafter 'Regulation 1408/71'). Cf. R. Cornelissen, 'The Principle of Territoriality and the Community Regulations on Social Security (Regulations 1408/71 and 574/72)', CMLRev 34 (1996): 439. It replaced Council Regulation No. 3 on social security for migrant workers, OJ 1958, 597. Regulation 1408/71 will itself be replaced by Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 Apr. 2004 on the coordination of social security systems, OJ 2004 L166/1, once the implementing Regulation of Regulation 883/2004 takes effect (this is expected for the end of 2009).

movement of workers of Article 42 EC). In these cases, the hand of the national authorities was forced by patients seeking what they considered to be better (including earlier) medical treatment in other Member States (hereinafter 'Member State of treatment') while claiming reimbursement of such treatment in accordance with the social security rules applicable in their home Member State (hereinafter 'Member State of affiliation').⁶ Adopting what has been called a patient-centered, needs-based approach,⁷ the ECJ has consistently supported such patient mobility. Because most Member States have been less than forthcoming in implementing this case law, it is the resulting need for codification that forms the Commission's primary justification for the Proposed Patients' Rights Directive.

Several aspects of this proposal are examined here.

In the first place, the process summarized previously suggests the occurrence of a familiar pattern in EU law where disparities between national markets lead to private litigation based on directly effective rights under the treaty that triggers Court intervention striking down national barriers – resulting in deregulation (or 'negative integration') – which is then duly followed by legislative proposals to fill the remaining and/or resulting gaps by new rules at EU level, concluding by re-regulation (or 'positive integration').⁸ This process of interaction between case law and legislation tends to involve both harmonization and liberalization of the applicable rules and a reassessment of the scope of legitimate public interest requirements. This paper will examine whether the proposed directive on patients' rights fit this mould.

In the second place, the following more specific questions will be addressed:

- Does the proposal form a codification of the patient mobility case law?
- Will the Proposed Patients' Rights Directive act as a catalyst for change?
- What is the scope and the role of patients' rights in the proposal?

First, the state of play of the patient mobility case law will be summed up briefly.

2. SUMMARY OF THE CASE LAW

In the course of its patient mobility case law over the past decade, the Court of Justice has developed a parallel regime for patient mobility based on the freedom to provide

⁶ This is the usage in the Proposed Patients' Rights Directive, which will be used throughout this text for reasons of consistency. The use of these terms runs parallel to that of the Member State of residence (also, competent Member State) versus Member State of stay in Regulation 1408/71, *supra* n. 6, and to the more general usage of home Member State and host Member State.

⁷ G. Davies, 'The Effect of Mrs Watts Trip to France on the National Health Service', *King's Law Journal* 18 (2007): 158, 160.

⁸ Cf. G. Davies, 'The Community's Internal Market-Based Competence to Regulate Healthcare: Scope Strategies and Consequences', *Maastricht Journal of European and Comparative Law* 14 (2007): 215. The distinction between negative and positive integration was pioneered by J. Tinbergen, *International Economic Integration* (Amsterdam: Elsevier, 1954), and developed for the EU by J. Pinder, 'Positive and Negative Integration: Some Problems of Economic Union in the EEC', *The World Today* 24 (1968): 88. Cf. F.W. Scharpf, 'Negative and Positive Integration in the Political Economy of European Welfare States', in *Governance in the European Union*, eds G. Marks et al. (London: Sage, 1996), 15; and 'The European Social Model: Coping with the Challenges of Diversity', *Journal of Common Market Studies* 40 (2002): 645.

services of Article 49 EC, alongside the preexisting rules based on the free movement of workers provided by Regulation 1408/71. The results are set out below.

*Table 1. Patient Mobility under Regulation 1408/71 and Article 49 EC
(as Interpreted by the ECJ)⁹*

	Free Movement of Workers: Article 42 EC/Regulation 1408/71	Free Movement of Services: Article 49 EC
Prior authorization for hospital care	Required	May be required if justified and proportional
Prior authorization for non-hospital care	Required	Not required
Means of payment	According to the rules of the Member State of treatment (may involve payment or co-payment by patient). Reimbursement of the Member State of treatment by the Member State of affiliation	By a patient with subsequent reimbursement in the Member State of affiliation
Level of reimbursement	According to the rules of the Member State of treatment. If reimbursement in the Member State of affiliation would be higher, the difference may be awarded based on Article 49 EC	According to the rules of the Member State of affiliation (but capped at the level of actual costs)

Greatly simplified, the case law can be summed up as follows.¹⁰ The scope of social security coverage as such is determined by the Member State of affiliation alone and therefore is not at issue, nor is the right of individual patients to seek treatment abroad and pay for it themselves at stake. Instead, the focus of both the Article 49 EC regime and that of Regulation 1408/71 is on the conditions for the reimbursement of treatment abroad, when a patient is in principle entitled to the treatment involved in his Member State of affiliation:

- The basis of reimbursement is easily stated: when Article 49 EC is relied on, reimbursement is at the level of domestic treatment in the Member State of

⁹ This table (based on that in the Impact Assessment, *infra* n. 12, 27) deals only with elective (planned) treatment and not with emergency treatment, which is covered exclusively by Regulation 1408/71 and, for obvious reasons, does not require prior authorization. Benefits and reimbursement in this case are governed by the rules of the Member State of treatment.

¹⁰ For a detailed survey, cf. T.K. Hervey, 'The Current Legal Framework on the Right to Seek Healthcare Abroad in the European Union', *Cambridge Yearbook of European Legal Studies* 9 (2007): 261.

- affiliation; based on Regulation 1408/71, reimbursement is at the level of the Member State of treatment. Where the latter is lower than the former, the difference may be claimed based on Article 49 EC.
- More complicated is the question of when patient mobility will be reimbursed. Based on Regulation 1408/71, prior authorization of treatment abroad is always required as a condition for reimbursement, that is, both for hospital and non-hospital care. Based on Article 49 EC, prior authorization – which is in principle a barrier to the freedom to provide services – cannot be required for non-hospital care. However, it may be required for hospital services. This is considered justified to safeguard the financial balance of the national social security system of the Member States and planning in the hospital sector.
 - So far, the Court has never required evidence before allowing this justification. Instead, it has focused on elaborating procedural guarantees concerning the objective and proportionate nature of the authorization process, notably fleshing out the concept of ‘undue delay’ by requiring due regard to the individual circumstances of each patient. Although these requirements are similar if not identical for the Article 49 EC setting and that of Regulation 1408/71, there is clearly a different starting point: Regulation 1408/71 always requires prior authorization, whereas in the case of Article 49 EC, Member States may, but need not, require prior authorization for hospital care and never for non-hospital care.

In this manner, the Court has balanced the public interest justifications invoked by the Member States with the rights of individual patients based on free movement. Against this background, the Proposed Patients’ Rights Directive will be discussed.

3. THE PROPOSED PATIENTS’ RIGHTS DIRECTIVE

3.1. RENEWING THE SOCIAL AGENDA

The Commission’s legislative proposal for a directive ‘on the application of patients’ rights in cross-border healthcare’, as presented on 2 July 2008, formed part of a raft of some twenty documents and proposals of the same date jointly billed as a renewed social agenda for twenty-first century Europe.¹¹ In stark contrast to the earlier attempt to embed patient mobility in the undiluted economic logic of the Services Directive, the connecting theme behind the July 2008 package was to constitute a counterpoint to

¹¹ Cf. Commission Communication of 2 Jul. 2008 on the ‘Renewed Social Agenda: Opportunities, Access and Solidarity in Twenty-First Century Europe’, COM (2008) 412 final; Commission press release IP/08/1070, ‘Commission Proposes Renewed Social Agenda to Empower and Help People in Twenty-First Century Europe’ (Brussels, 2 Jul. 2008); Commission memo MEMO/08/471, ‘Renewed Social Agenda: The Elements of the Package’ (Brussels, 2 Jul. 2008).

the Lisbon growth strategy of the EU, that is, to develop further the social conscience of the EU brand of capitalism.

It is beyond the remit of this paper to comment on these broader ambitions, and it remains to be seen whether patient mobility will in fact fare better in the context of the social agenda. Member States that are afraid their social security systems will unravel as a result of this proposal are unlikely to spot any obvious social dimension in it. Another difference between the Proposed Patients' Rights Directive and the ill-fated earlier attempt to include a single article on healthcare in the Services Directive is that the current proposal is a full-fledged dedicated legal instrument purporting to provide a complete and coherent legal regime for all the issues involved; the Commission is now staking a far more ambitious claim.

3.2. IMPACT ASSESSMENT: QUANTIFYING THE CASE FOR CODIFICATION

The proposal for the patients' rights directive was published jointly (inter alia) with an Impact Assessment that the Commission used to choose between different policy options.¹² It is discussed here insofar as it provides a useful background to the proposal. The Impact Assessment states that over the past twelve months, 4% of the EU population has received medical treatment in another Member State, 70% of the EU population believes such treatment would be reimbursed, and just over half of the EU population is open to traveling to another EU Member State to receive treatment.¹³ However, it also states that generally patients will prefer to receive care in their local environment and that it is generally considered to be safer and more efficient to be treated within a single (national) healthcare system with the exception of three cases:

- highly specialized care;
- border regions (where the nearest provider may be across the border);
- where there is lack of capacity locally and capacity is available in another Member State.

The Impact Assessment further states that cross-border healthcare accounts for 1% of public healthcare expenditure, that is, approximately EUR 9.7 billion.¹⁴ Hence, the overall impact of patient mobility in the EU is small, although its local impact may be much greater for example, in border regions, smaller Member States, in tourist areas, and in systems or for treatments involving high co-payments (out of pocket expenses for patients leading them to seek less costly treatment abroad).

¹² *Supra* n. 1 (with an Explanatory Memorandum); Commission staff working document of 2 Jul. 2008, accompanying document to the Proposed Patients' Rights Directive: Impact Assessment, SEC (2008) 2163.

¹³ Impact Assessment, *supra* n. 12, 6–7 citing Flash Eurobarometer series #210, Cross-border health services in the EU, Analytical report for DG Sanco, 2007.

¹⁴ EU GDP is EUR 12,149 billion of which presently 7.6% (EUR 967 billion) is spent on public healthcare. See Impact Assessment, *supra* n. 49 (Eurostat figures 2006/2007).

Overall, the Impact Assessment identifies 'a rising trend for cross-border healthcare and significant potential demand from citizens to explore cross-border healthcare where it is quicker, better, cheaper or more convenient for them'.¹⁵ Such a trend would be consistent with prospects of demand-driven markets generating greater overall efficiency as consumer choice rewards providers who perform better, providing an incentive for providers more generally to improve their performance. In this context, it is worth noting that the Impact Assessment estimates the average pent-up demand, or unmet healthcare needs, in the EU affects 8.5% of its population (of which 8.5%, only 10% receive care abroad).¹⁶

Following standard Commission practice, the Impact Assessment provides a quantified comparison of four different policy options:

- no action at Community level;
- non-binding guidance on cross-border healthcare issues;
- providing a general legal framework through a directive either covering both hospital and non-hospital services or only non-hospital services;
- a detailed legal framework of harmonizing legal measures.

Assessing the validity of the quantification involved is better left to health economists. In any event, the Impact Assessment shows that only the option eventually chosen by the Commission – that of a dedicated directive covering both hospital and non-hospital care – provides net benefits in relation to the costs involved, more specifically a positive balance of EUR 179.6 million, with 780,000 extra patients receiving treatment for the EU as a whole.

Because the other options provide only negative benefits (to greater and lesser degrees), they must obviously be discarded. However, the gains claimed in relation to the preferred policy option appear rather small as a basis for making the case for EU action. There is a contradiction at play here. As will be seen below, the Commission uses the minor impact that patient mobility is expected to have in order to argue that prior authorization requirements are unlikely to be justified. It struggles with the need to argue, on the one hand, that something meaningful is at hand requiring EU legislation and, on the other hand, that the impact of this legislation on national social security regimes will be small enough to block prior authorization requirements that could frustrate the initiative.

Possible justifications for these contradictory claims appear to be:

- the principled argument that this is required to enable patients to actually enjoy the rights that were conferred upon them by the treaty itself;
- a more opportunistic approach, which assumes that this is merely the first step toward creating further incentives for greater efficiency in healthcare, setting in motion a process that will be difficult to halt once started.

¹⁵ *Ibid.*, 11.

¹⁶ *Ibid.*, 11–12.

Most likely, these motives have been mixed.

In this context, it is significant that the Impact Assessment finds differences in efficiency to be as great within Member States as they are between different Member States.¹⁷ Clearly, there is a lot to gain merely by spreading best practice, and the fact that there are such barriers to doing this even within national systems suggests that there may well be a role here for the EU.

3.3. THE DYNAMICS OF 'OLD' AND 'NEW' PATIENT'S RIGHTS

'Patients' rights', the title chosen by the Commission for its proposed directive, refers to a concept generally understood as being much broader in scope than the reimbursement of cross-border medical treatment, that is, considerably broader than the old patients' rights that the Court of Justice had developed in its patient mobility case law.¹⁸

In the context of the Proposed Patients' Rights Directive, this broader concept is primarily linked to the common principles that are framed as obligations of the Member State of treatment. These include quality and safety standards, access to the information necessary for informed choice (i.e., transparency), the means to complain and obtain remedies (i.e., accountability), and compensation for harm and privacy rights and can in effect easily be rephrased as a set of new and potentially highly significant patients' rights. This is so because the scope of these new rights appears to cover all patients, not merely mobile ones (although their creation was triggered by the latter).

A dynamic seems to be at work with old patients' rights engendering new ones, which will be examined further below.

3.4. STRUCTURE

Five aspects of the Proposed Patients' Rights Directive are briefly discussed here:

- legal basis and general principles;
- scope;
- the relationship with social security Regulation 1408/71;
- common principles in EU health systems: the new patients' rights;
- prior authorization and cross-border healthcare: the old patients' rights.

Next, a more in-depth analysis will focus on the last two of these, which are the most salient aspects of the proposal, and will look at future prospects.

¹⁷ *Ibid.*, 42-44.

¹⁸ Cf. World Health Organization, <www.who.int/genomics/public/patientrights/en/>.

4. LEGAL BASIS AND GENERAL PRINCIPLES

4.1. HARMONIZATION

The Proposed Patients' Rights Directive is based on Article 95 EC, that is, the harmonization provision aimed at securing the establishment and functioning of the internal market.¹⁹ This is justified by the fact that, although the Court judgments clarified patients' rights, they have not proven sufficient in and of themselves to enable patients to avail themselves of these rights widely or in an effective manner. That is, they have so far been frustrated by the Member States.

4.2. SUBSIDIARITY

At the same time, the Proposed Patients' Rights Directive is required to respect not just the general subsidiarity provision in Article 5 EC but also the provisions of Article 152, paragraph 5 EC, which provides a special subsidiarity clause with respect to the responsibility of the Member States for the organization and delivery of healthcare. As was already clarified by the Court in *V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA* and *Watts*, this provision does not mean that adjusting national systems may not be required by other treaty obligations, such as Article 49 EC.²⁰

In this context, the proposed directive aims to form a framework that:

- first, provides clarity about the rights to reimbursement for healthcare provided in other Member States;
- second, ensures that such cross-border healthcare is of high quality, safe, and efficient, which could not be done effectively by individual Member States.

The basic assumption however is that, in line with Article 152 EC, the Member States retain full responsibility for determining what medical services are covered by their national social security regimes and for the actual provision of healthcare.²¹

4.3. PROPORTIONALITY

The Commission claims that its proposal respects the proportionality requirement of Article 5 EC because the Member States (as under the subsidiarity argument) retain

¹⁹ On the relevant legal basis, cf. D. Wyatt, 'Community Competence to Regulate Medical Services', in *Social Welfare and EU Law*, eds M. Dougan & E. Spaventa (Oxford: Hart, 2005), 131.

²⁰ Case No. C-385/99 *Müller-Fauré*, *supra* n. 4, para. 102 (without specific reference to Art. 152, para. 5 EC); Case C-372/04 *Watts*, *supra* n. 4, para. 147.

²¹ The body of the proposal lacks a clear affirmation of the autonomy of the Member States with regard to the scope of their respective national social security coverage. Cf., however, Recitals 25 and 26 of its Preamble and Art. 6, para. 1.

the right to determine the healthcare benefits for which their citizens are eligible. Moreover, Article 6 paragraph 4 of the Proposed Patients' Rights Directive provides that, in so far as they are the same for care provided in the Member State of affiliation or another Member State, are non-discriminatory, and do not obstruct the free movement of persons, Member States may continue to impose conditions, criteria of eligibility, and regulatory and administrative formalities on patients seeking healthcare. An example is the obligation to obtain a referral from a general practitioner before seeking specialized care.

5. SCOPE

The scope of the Proposed Patients' Rights Directive extends to all healthcare without distinction including both healthcare within the terms of Article 152 paragraph 5 EC as well as healthcare provided outside social security systems, such as private healthcare. These points are made explicit in the definition of healthcare in Article 4, subparagraph (a) of the Proposed Patients' Rights Directive:

healthcare means a health service provided by or under the supervision of a health professional in the exercise of his profession, and regardless of the ways in which it is organized, delivered and financed at national level or whether it is public or private.

The explanation of the definition of cross-border healthcare²² in Recital 10 of the Preamble is also worth noting:

For the purpose of this Directive, the concept of 'cross-border healthcare' covers the following modes of supply of healthcare:

- Use of healthcare abroad (i.e.: a patient moving to a healthcare provider in another Member State for treatment); this is what is referred to as 'patient mobility';
- Cross-border provision of healthcare (i.e.: delivery of service from the territory of one Member State into the territory of another); such as telemedicine services, remote diagnosis and prescription, laboratory services;
- Permanent presence of a healthcare provider (i.e.: establishment of a healthcare provider in another Member State); and,
- Temporary presence of persons (i.e.: mobility of health professionals, for example moving temporarily to the Member State of the patient to provide services).

Again, the Commission claims a broad scope although only the first of these aspects is in fact dealt with in the Proposed Patients' Rights Directive. Three of the modes of supply mentioned are related to the provision of services. Yet, as will be argued below, the one concerning the freedom of establishment is likely to become the most important in the follow-up to the proposal.

²² 'Cross-border healthcare' means healthcare provided in a Member State other than that where the patient is an insured person or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established. Art. 4 (b), Proposed Patients' Rights Directive.

6. PARALLEL REGIMES BASED ON ARTICLE 49 AND ARTICLE 42 EC CONTINUED

6.1. THE RIGHT TO TREATMENT

The EU will continue to have two parallel regimes for the authorization and/or reimbursement of cross-border healthcare:

- one is the existing regime based on Regulation 1408/71;
- the other is the new regime of the Proposed Patients' Rights Directive, replacing that directly based on Article 49 EC (never implemented in most Member States).

As before, the relationship between the two is less than straightforward.

The Court had effectively merged the two regimes as far as the right to treatment was concerned, based on the 'undue delay' criterion, first effectively in the *Patricia Inizan v. Caisse primaire d'assurance maladie des Hauts-de-Seine* (hereinafter '*Inizan*') case,²³ and then explicitly in *Watts*:²⁴

there is no reason which seriously justifies different interpretations depending on whether the context is Art. 22 of Regulation No 1408/71 or Art. 49 EC, since in both cases the question is (...) whether the hospital treatment required by the patient's medical condition can be provided on the territory of his Member State of residence within an acceptable time which ensures its usefulness and efficacy.

This connection is now broken. The rule established in the patients' rights directive is that, in cases of undue delay, Article 22 of Regulation 1408/71 applies, and in all other cases, the regime of the proposed directive.²⁵ In effect, the undue delay case law of the Court in relation to Article 49 EC is dropped from the codification program, and at the same time, the scope of Regulation 1408/71 is reduced to cases of 'undue delay'. This criterion is of questionable practical use because it will require, at least in non-obvious cases (the number of which will depend largely on the willingness of the authorities involved), making an application under Article 22 of Regulation 1408/71 to find out if in fact there is 'undue delay' and therefore which regime is applicable. Perhaps this objection will be less relevant if in practice few if any prior authorizations are (or can be) required based on the Proposed Patients' Rights Directive. However, is anything gained hereby worth abandoning the principles hard-won in the case law?

²³ Determining undue delay requires 'to have regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time when authorisation is sought and, where appropriate, of the degree of pain or the nature of the patient's disability which might, e.g., make it impossible or extremely difficult for him to carry out a professional activity, but also of his medical history'. Case No. C-56/01 *Inizan*, *supra* n. 4, para. 46 with reference to Case No. C-157/99 *Geraets-Smits and Peerbooms*, *supra* n. 5, para. 104, and Case No. C-385/99 *Müller-Fauré*, *supra* n. 4, para. 90.

²⁴ Case No. C-372/04 *Watts*, *supra* n. 4, para. 60.

²⁵ Art. 3, para. 2 and Art. 9, para. 1.

6.2. THE RIGHT TO REIMBURSEMENT

Second, the basis for reimbursement (at the level prevailing in the Member State of treatment for Regulation 1408/71 and at that of the Member State of affiliation for Article 49 EC, or now the Proposed Patients' Rights Directive) will continue to differ under the two regimes. Whereas under Regulation 1408/71, the general rule is that patients do not have to meet the costs of treatment directly, under the regime of the Proposed Patients' Rights Directive, payment by the patient subject to subsequent reimbursement is the rule. As far as the benefits themselves are concerned, the Preamble to the Proposed Patients' Rights Directive suggests that patients may choose which mechanism they prefer.

There are at least two reasons why this approach is questionable:

- First, little if any actual choice may be available because the Proposed Patients' Rights Directive determines that patients who wish to rely on 'undue delay' arguments must seek recourse to Article 22 of Regulation 1408/71, and in all other cases that the Proposed Patients' Rights Directive applies, so few cases of parallel applicability appear to exist.
- Second, which regime is more favourable will differ for each particular combination of Member State of affiliation and of treatment, not to mention for the type of treatment involved in a particular case! Clarity on this issue will not increase as a result of the Proposed Patients' Rights Directive. It is therefore not clear either whether mobile patients are likely to see a net improvement in their level of reimbursement.

Under the proposal, the most important difference between the parallel regimes will be whether prior authorization can be required in the first place; whereas it is always required in case of Regulation 1408/71, the scope for prior authorization based on the proposed directive will be much more limited, as will be seen below.

6.3. WOULD AN AMENDMENT OF THE SOCIAL SECURITY RULES SUFFICE?

These observations raise the question whether a separate directive is in fact necessary and whether amending Regulation 1408/71 (read its successor Regulation 883/04) would have sufficed instead, for example, by simply providing that the more favourable of the two funding regimes applies and by codification of key elements of the case law. It is of course the Court itself that opened up these parallel tracks in *Kohll* before making them converge again in cases such as *Inizan* and *Watts*. However, would it be impossible to satisfy the Court that Article 49 EC could adequately be addressed based on incorporating the key elements of its own case law in the social security regulations? In addition, would this not have been logically consistent with the aim of strengthening the renewed social agenda?

The Commission has not addressed this issue squarely; the Impact Assessment did not consider extending and/or amending the existing social security regulations.

If codification had been the objective, this would have been the straightforward solution. Opting for an Article 49 EC Directive therefore reveals ambitions beyond codification.

7. COMMON PRINCIPLES FOR HEALTHCARE: THE NEW PATIENTS' RIGHTS

7.1. RIGHTS TO ACCOUNTABILITY AND TRANSPARENCY

The main innovation in the Proposed Patients' Rights Directive is that its Article 5 sets out common principles for healthcare that can be seen as a new set of patients' rights. These correspond with the responsibilities of the Member States of treatment and are not based on the free movement case law of the Court. Instead, the principles are based on Council Conclusions of 2006 to the same effect,²⁶ which drew on the existing systems (or at least ambitions) of the Member States and should therefore, according to the Explanatory Memorandum, not require major adaptations.

However, by incorporation in the Proposed Patients' Rights Directive, these principles are now made binding on the Member States and will therefore presumably become justiciable in some form. Universality, access to high-quality care, equity, and solidarity are asserted as the guiding principles for Member States of treatment.²⁷

This is not new in relation to the previously mentioned Council Conclusions, but it is noteworthy that the Commission should propose to promote in particular equity and solidarity from such a grand but non-committal setting to a binding measure of Community law. This raises the question on what these objectives and principles could mean if (as is nominally not disputed) the power to define the scope of benefits and of access to them, as well as their funding, remains at national level. Likewise, it will be interesting to see how these prerogatives of the Member States can be squared with EU legislation that amounts to promoting universal access to high-quality care, at least assuming the latter is not merely defined as that which is actually provided at any given time.

Consistent with Article 152 paragraph 5 EC, the Proposed Patients' Rights Directive starts by setting out the key principle that the Member State of treatment bears responsibility for the organization and delivery of healthcare. In substance, it mainly requires the Member States of treatment to provide quality and safety standards for healthcare based on dynamic international best practice standards (the application of which is monitored and enforced) and to ensure the right to the information necessary for an informed choice; the right to make complaints and guarantees of redress and remedies; and the right to privacy, equal treatment, and non-discrimination. The right to an informed choice involves in particular information about availability, prices, and outcomes of healthcare. Finally, the Member State of treatment is obliged to provide for

²⁶ Council Conclusions on common values and principles in European Union health systems, OJ 2006 C146/1 (Statement in Annex).

²⁷ This corresponds with the overarching values identified, *Ibid.*, para. 6. The Council had resisted earlier proposals to define patients' rights at EU level. Cf. T.K. Hervey, 'The Legal Basis of European Community Public Health Policy', in *The Impact of EU Law on Health Care Systems*, eds M. McKee, E. Mossialos & R. Baeten (Brussels: PIE.-Peter Lang, 2002), 46-47.

adequate systems of liability insurance. Although not phrased as such, it is clear that each of these obligations on the Member States can be read as conferring equivalent rights on patients.

7.2. UNIVERSAL APPLICABILITY FOR THE NEW PATIENTS' RIGHTS?

Remarkably, the scope of this important provision is not clearly defined:

- The Council Conclusions on which the text is based is clearly of general application.
- The Preamble of the proposal and its explanatory memorandum focus on the justification that confidence-building measures for mobile patients are at stake.
- The heading ('Member State of treatment') suggests norms that apply for patients from other Member States.
- The wording (referring to healthcare in general and not to cross-border healthcare) of Article 5 itself implies a general application.

Because it is difficult to see how such fundamental norms of accountability and transparency could possibly be implemented solely for the benefit of patients from other Member States, it is assumed here that they are universal rights that will apply to all patients, not just those moving across borders. This is also how they are phrased in Article 5 itself, which therefore involves a major step in terms of accountability to patients, and by healthcare providers.

While these new patient rights identified above are not elaborated or integrated further on in the proposal, paragraph 3 of Article 5 provides that the Commission shall develop guidelines for its implementation in cooperation with the Member States, that is, not based on the 'comitology' procedures established in other provisions of the proposed directive but on an ad hoc form of cooperation between the Commission and high officials representing the Member States. Given the nature and the range of topics involved as well as the rephrasing of the Member States' obligations as universal patients' rights, this provision is likely to give rise to dynamics that could lead to significant further harmonization across the EU.

The implications of this will be discussed in more detail in the last section.

7.3. NO SAFEGUARDS FOR MEMBER STATES OF TREATMENT: WHAT ARE THE IMPLICATIONS?

Although the Proposed Patients' Rights Directive contains provisions to allow (at least in theory) a derogation from free movement to the Member State of affiliation in the shape of prior authorization requirements, it foresees none for the Member State of treatment. The position taken in the proposal is that of strict non-discrimination:

Patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including protection provided for according to Community law and national legislation in force in the Member State of treatment.²⁸

This appears to be a categorical statement that no form of preference can be given to domestic patients except on medical grounds (i.e., not based on financial or planning considerations).²⁹

This is significant, as in the absence of tariff rebalancing, it may clearly happen that charges for treatment of patients from other Member States are out of line with actual costs but attractive to the healthcare provider in question (e.g., to 'fill empty beds'). In such cases, payment is likely to cover only marginal costs rather than a share of fixed costs, putting pressure on public funding. Meanwhile, competition between healthcare providers to attract mobile patients is likely to trigger new dynamics feeding through into the national market.³⁰ On the one hand, such developments could well contribute to undermining the financial sustainability and coherence of the existing national social security systems while on the other hand contributing to pressure toward much needed rationalization and rebalancing. Consequently, the impetus toward change as a result of the Proposed Patients' Rights Directive is likely to involve Member States in their role as Member States of treatment, not just as Member States of affiliation.

8. THE FRAMEWORK FOR CROSS-BORDER HEALTHCARE: THE OLD PATIENTS' RIGHTS

This section concerns the codification of the Court's patient mobility case law.

8.1. REIMBURSEMENT OF ACTUAL COSTS

As a counterpoint to the obligations of the Member State of treatment set out in Article 5 of the Proposed Patients' Rights Directive, its Article 6 sets out a number of obligations on the Member States of affiliation in relation to patients ('insured persons') traveling to other Member States for treatment that is covered by the benefits to which they are entitled in their Member State of affiliation. The most important of these obligations is that the Member States of affiliation must reimburse the actual costs for such treatment up to the level applicable to the same or similar treatment in the Member State of affiliation.

²⁸ Art. 5, para. 1, subpara. (g). Recital 13 also states 'Member States may differentiate in the treatment accorded to different groups of patients only where they can demonstrate that this is justified by legitimate medical grounds (...).'

²⁹ This is remarkable in the view of some commentators that 'host states are entitled ... to discriminate directly or indirectly on the basis of nationality as regards access to welfare benefits, ... without exposing themselves to the possibility of a legal challenge by adversely affected temporary visitors relying upon Art. 49 EC'. Dougan & Spaventa (eds), "'Wish you weren't here ...' New Models of Social Solidarity in the European Union', *supra* n. 19, at 197, with reference to the patient mobility case law.

³⁰ This competition is not limited to the EU or even to 'developed' countries as increasingly elite hospitals in Asia and Latin America are attracting Western patients. Cf. 'Briefing on Globalization and Health Care: Operating Profit', *The Economist* (2008): 66–68.

It should be highlighted that in the future, Member States of affiliation will also be required to have a mechanism for the calculation of such costs, which must be based on objective, non-discriminatory criteria that are known in advance.³¹ This seemingly self-evident requirement is likely to have far-reaching consequences especially for benefits in kind and National Health Service (NHS) systems that in most cases are likely to lack useful preexisting cost information on which reimbursement can be based. Given the immense difficulties associated with the introduction of sound cost-accounting principles in other industries where such practices were not already in place (notably in the context of the liberalization of the various utilities), the effort required is likely to be commensurate, may give rise to significant litigation, and may have unexpected side effects in highlighting cross-subsidies and inefficiencies that had so far remained hidden. Although this suggestion is unlikely to be popular, it may well be that a common EU understanding of the relevant costing principles will be required before long.

8.2. NON-HOSPITAL CARE: FULL LIBERALIZATION

Patients are entitled to seek non-hospital care that is covered by their national social security regime in other Member States without prior authorization and are entitled to reimbursement at the level as if the care had been provided in the Member State of affiliation. It is assumed therefore that this will by definition not undermine the financial equilibrium of social security systems.

8.3. HOSPITAL CARE AND SPECIALIZED CARE: THE END OF PRIOR AUTHORIZATION REGIMES?

Article 8 of the Proposed Patients' Rights Directive governs hospital care and specialized care.³² In contrast to non-hospital care, the Member State of affiliation may impose a prior authorization requirement under the following conditions:

The Member State of affiliation may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State where the following conditions are met:

- (a) had the healthcare been provided in its territory, it would have been assumed by the Member State's social security system; and
- (b) the purpose of the system is to address the consequent outflow of patients due to the implementation of the present Art. and to prevent it from seriously undermining, or being likely to seriously undermine:
 - (i) the financial balance of the Member State's social security system; and/or

³¹ Cf. Case No. C-358/99 *Müller-Fauré*, *supra* n. 4, para. 107; Case No. C-372/04 *Watts*, *supra* n. 4, para. 143. Cf. Davies, *supra* n. 7, 164-165.

³² Hospital services and specialized care concern healthcare that requires an overnight stay (for one or more nights) or that is included on a limited list that is established according to comitology procedures and involves the use of highly specialized and costly medical infrastructure or equipment or involves treatments that present a particular risk to the patient or the population at large.

- (ii) the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.

Moreover, a prior authorization system must be limited to what is necessary and proportionate and may not constitute a means of arbitrary discrimination.

At first sight, this may merely appear to represent a faithful transcription of the case law. It is not. The Court was so far content to assume that if the previously mentioned grounds were invoked in the context of hospital care, requiring prior authorization could be considered necessary and reasonable and then focusing on the procedures and conditions for authorization (including criteria when authorization must be granted based on 'undue delay', on which more is provided below).³³

What is intended here is something very different: the Member States will now have to provide actual evidence that the outflow of patients due to cross-border hospital care seriously undermines their social security system or planning in the hospital sector. However, the Commission clearly believes that these data do not exist and is in fact proposing that the directive should state so explicitly. Thus, Recital 31 of the Preamble now reads:

The evidence available indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover guaranteed by the statutory sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems.³⁴

This means that the burden of proof would be shifted fundamentally, and the Commission has increased it further by providing up-front its own evidence to the contrary (albeit in general terms). Few if any Member States may be expected to dispose of the data required to back up a prior authorization requirement at present, and, if the Commission is right, their chances of doing so in the future are slim. However, because the Proposed Patients' Rights Directive provides no procedure to settle whether the required standard is actually met, this will have to be decided in the course of private litigation and infringement procedures that are likely to be costly and time-consuming. Yet surely it cannot be the purpose of new EU legislation on this issue to set the stage for years of conflict? In any event, it appears likely that this aspect of the proposal will lead to lively discussions if there are any Member States left who wish to maintain prior authorization requirements.

³³ E.g., Case No. C-372/04 *Watts*, *supra* n. 4, para. 110; Case No. C-385/99 *Müller-Fauré*, *supra* n. 4, para. 81; Case No. C-157/99 *Geraets-Smits and Peerbooms*, *supra* n. 4, para. 80.

³⁴ Likewise, in its Explanatory Memorandum (*supra* n. 12, 16) the Commission clearly states that based on its Impact Assessment, 'there is no evidence to suggest that such care [hospital care] will undermine the financial sustainability of health and social security systems overall or the organization, planning and delivery of health services'. *Ibid.*, 14: 'The evidence available as set out in the impact assessment indicates that the application of free movement principles regarding use of healthcare in another Member State within the limits of the cover or the sickness insurance scheme of the Member State of affiliation will not undermine the health systems of the Member States or financial sustainability of their social security systems', i.e., not undermine at all, let alone seriously.

8.4. UNDUE DELAY DROPPED IN ARTICLE 49 EC CONTEXT

Finally, Article 9 of the Proposed Patients' Rights Directive codifies and somewhat extends the procedural guarantees that the Court has set out in its case law. These are the familiar categories of objective, transparent and non-discriminatory criteria, necessity and proportionality, access to judicial review, and so forth.³⁵

In this context, it is remarkable that the substantive criteria from the 'undue delay' case law (medical condition, degree of pain, nature of the disability involved, and ability to carry out a professional activity) are now listed only as factors that the Member States must take into account 'when setting out time limits within which requests for the use of healthcare in another Member State must be dealt with'.³⁶

This is remarkable because the point of the 'undue delay' criteria as intended by the Court in its patient mobility case law on Article 49 EC and Regulation 1408/71 alike was to establish when authorization *must* be granted, not to promote the superior design of waiting lists. The basic idea driving the Court's rulings on this matter was that, under some circumstances, the treaty provides patients with a right to treatment abroad that can no longer be trumped by a public policy justification or by an overriding reason of general interest. How can the Proposed Patients' Rights Directive possibly misconstrue this most crucial patients' right as it now does? The medical condition and the degree of pain involved, *inter alia*, should determine how a request is dealt with on substance, that is, its outcome, and not merely how long one should be made to wait before a request is dealt with at all, based on criteria that remain unspecified. If the prior authorization process is to be taken seriously – and clearly, it should be if the proposal includes the possibility of having it (even if the Commission appears to believe there will be no prior authorization requirements) – then the criteria for granting or refusing authorization should be set out in the directive itself. The undue delay criteria set out by the Court may not be perfect, but they would certainly be a good place to start from.

If this requires redefining the delineation between the proposed directive and Regulation 1408/71, then it seems to be a price well worth paying.

9. FURTHER ANALYSIS

The development of the law on patient mobility does appear to fit the mould of the standard interaction between positive and negative integration: first national measures

³⁵ Art. 9 para. 1 states that where the conditions for the application of Art. 22 of Regulation 1408/71 are met, the authorization pursuant to this Regulation shall be granted: presumably, this is meant to reinforce the rule in Art. 3 para. 2 that if the conditions where authorization under the Regulation must be granted are met, the provisions relative to patient mobility of the Proposed Patients' Rights Directive do not apply.

³⁶ Art. 9 para. 4. Recital 33 of the Preamble suggests that 'patients should normally have a decision regarding the (sic) cross-border healthcare within fifteen calendar days' and 'that period should be shorter where warranted by the urgency of the treatment in question'. If achieving this is what is intended by Art. 9 para. 4 of the proposal, simply setting a two-week deadline with an exception for emergencies and retaining the familiar criteria for whether to award authorization or not would be more appropriate.

obstructing the freedom to provide services (in this case) are struck down by the Court, and then the need arises for reregulation to fill the gap left, providing sufficient consensus for a more liberal community regime to emerge. This will be illustrated by a more detailed discussion of the following three topics:

- the difficulties of defending prior authorization requirements based on the proposed patient mobility directive;
- the scope for change based on the new patient's rights introduced by the proposal; and
- possible future developments.

9.1. PRIOR AUTHORIZATION REQUIREMENTS: LIBERALIZATION

The liberalization dimension of the Proposed Patients' Rights Directive is clear where it fleshes out the prohibition of Article 49 EC. It does so *inter alia* by undermining *ex ante* the prospects of prior authorization regimes not just by requiring evidence that they are necessary and proportionate (rather than accepting them as justified in principle provided the right grounds are invoked as the Court had done) but also by incorporating an initial assessment that there will be no serious effects on the social security systems of the Member States (based on supporting evidence, such as that on average only 1% of healthcare expenditure is affected).

The practical difficulties of actually demonstrating the need for a prior authorization system are in any event considerable. Justifying prior authorization raises a number of questions:

- How in a sector where the cost of an individual treatment is not known can it be plausibly argued that transferring such treatments abroad would jeopardize the financial balance of the system? In such a case, the balance would appear to be threatened by the lack of information about the system itself.
- Moreover, how can we demonstrate that the financial balance of a social security system is threatened if other basic measures of sound administration and business practice (starting from cost accounting and tariff rebalancing) are not taken first or at least in tandem?
- And who could credibly argue in favour of preserving the status quo at the expense of patients who could be helped more efficiently abroad while ignoring systemic failure at home, especially if the latter was to be more fully exposed in the process?
- It may well be that raising such issues will be the primary benefit of any attempts to introduce prior authorization under the Proposed Patients' Rights Directive. Or perhaps, more cynically, will the Member States prefer to forego the introduction of prior authorization requirements to avoid exposing themselves in this manner?

At the same time, the Proposed Patients' Rights Directive does not form a strict codification of the case law in more worrying respects as well. By creating a division of labour whereby 'undue delay' cases are dealt with exclusively under the social security regulations (based on the free movement of workers) and everything else falls under the Proposed Patients' Rights Directive, it guts the 'undue delay' case law on Article 49 EC of the Court without providing an alternative standard for approving or denying authorizations – the relevant criteria are to be developed nationally. Unless authorization regimes based on the Proposed Patients' Rights Directive fail to arise at all – for example, for the reasons given above – this seems a recipe for trouble. On a more principled note, it appears difficult to justify signing away hard-won patients' rights based upon the directly effective treaty freedoms in this manner just in order to settle a boundary dispute with the social security regulations.

9.2. NEW PATIENTS' RIGHTS: HARMONIZATION

Harmonization is found in the main innovation of the proposal in relation to the case law, which are the obligations of Member States of treatment, or new patients' rights. These are likely to ensure the enduring impact of patient mobility on Member States both when sending patients abroad and when receiving them. The obligations involved have their origins in Council Conclusions of 2006,³⁷ but if the Proposed Patients' Rights Directive is adopted, they will be made legally binding and justiciable. Moreover, the ensuing rights – especially to accountability and transparency on availability, prices, and outcomes of healthcare – will accrue not just to mobile patients but to all patients in each Member State. Arguably, this would be – or would become – the key element of positive integration to be introduced by the Proposed Patients' Rights Directive. In sum, the addition of the broader new patients' rights (to accountability and transparency) to the codification of the old patients' rights to reimbursement could create momentum for broader change, including in the direction of market-led efficiency.

Potentially, we are therefore looking at a chain of events leading toward fundamental change. The links of this chain are the following:

- (1) the creation of rights to reimbursement for treatment abroad in the patient mobility case law of the Court;
- (2) the creation of rights to a certain standard of treatment abroad by the proposed directive;
- (3) the extension of these rights to patients treated at home by the proposed directive; and
- (4) the leveraging of these rights (especially in terms of transparency and accountability) to begin transforming national healthcare systems (a so far hypothetical dynamic).

³⁷ *Supra* n. 26.

The Guidelines that the Commission proposes to develop in cooperation with the Member States in this context could be a catalyst for further change. However, the pace of change may well be driven by further litigation based on patients' rights.

By choosing the legislative route on patient mobility, the Commission is taking a calculated risk. This risk is that, in the process of law making, the relatively clear-cut and far-reaching case law of the Court based on Article 49 EC itself – and therefore at present unassailable by reluctant Member States – will be diluted. As has been indicated above, the Commission's proposal itself shows that this dilution is taking place already. Realistically, however, the stratagems that can be deployed at national level in order to frustrate patients actually availing themselves of their rights under EU law, no matter how well grounded in the treaty these might be, are almost endless. Hence, the Commission is probably right in its assessment that to give teeth to patient mobility based on Article 49 EC, secondary law is required, although it has not explained why this could not have been done by extending the existing social security regulations.

The explanation proposed here is that the Proposed Patients' Rights Directive incorporates a number of elements designed to set in motion further changes in healthcare systems at national level, to a significant degree precisely based on 'patients' rights', which will in the longer term promote both greater efficiency and accountability. For those who think these things are desirable, the Proposed Patients' Rights Directive is therefore clearly a first step in the right direction. At the same time, the fact that the focus both of the recent case law and of the proposed directive has been centered on the patient fits well within a consumer (and/or citizen)-oriented approach to European integration and is consistent with the social policy agenda that is being developed as a response to public scepticism about the benefits of the EU, just as it would be in line with a demand-based economic view. That does not make this proposal immune to criticism from those who fear that any form of change may erode national solidarity (nor from those who simply represent vested interests). However, it is consistent with most perspectives that accept the potential of a positive role for the EU.

9.3. FUTURE DIMENSIONS

Before concluding, it is worth recalling that patient mobility is strictly speaking only one of four possible types of cross-border healthcare that the proposed directive purports to deal with. These are:

- the use of services abroad (patient mobility);
- cross-border provision of services (such as might be based on e-medicine);
- temporary mobility of health professionals; and
- the permanent establishment of healthcare providers in other Member States.

Patient mobility provides the substance of the Proposed Patients' Rights Directive alongside patients' rights that do not fit in these four categories as they are universal.

The other three types of cross-border healthcare are not addressed. However, it is arguably the freedom of establishment that could next introduce a salutary dose of competition to healthcare systems throughout the EU:

- In many Member States, parallel systems of public and private provision of healthcare raise issues about discrimination in funding deterring entry (which for entrants from other Member States will almost invariably take place in the private sector), given that accurate costing and pricing are almost unknown in the public healthcare sector.
- Even in systems that are nominally wholly private, the same will de facto hold for incumbents vis-à-vis prospective entrants.
- Likewise, constraints, for example, on the distribution of dividends or requiring non-profit status form de facto entry barriers for newcomers who must by definition attract outside capital (and would use it to build more efficient facilities).³⁸

Although the Proposed Patients' Rights Directive as it now stands contains nothing of substance on establishment, it may well add to a new dynamism on this dimension too. Apart from any new patient flows, the effects of patients' rights to accountability and transparency as well as reimbursement of actual costs are likely to spill over into the relations between providers of care and regarding their funding.

In this context, elements missing from the proposed directive that would fit in with patient mobility but are also significant in the context of establishment are defining services of general economic interest for healthcare and standardization of the diagnosis-related groups (DRGs) that are the basic costing and accounting units in most modern healthcare systems. Defining services of general economic interest is a crucial step toward setting out public service objectives in terms of consumer rights and ensuring that any related ancillary restrictions are proportional thereto. It is therefore key both to rationalization and to promoting market entry in healthcare. DRGs that were either standardized or based on common principles would be immensely useful for transactions and reimbursements across borders, would increase transparency (exposing differences in efficiency), and would likewise facilitate entry, not just of healthcare providers but also of health insurers.

10. CONCLUSION

As the first EU level initiative toward liberalization and harmonization of healthcare services, the Proposed Patients' Rights Directive is both more and less than a faithful codification of the preceding patient mobility case law of the Court of Justice:

- It is less because it abandons the Court's undue delay criterion and, instead of further convergence between the two regimes based on the freedom to

³⁸ E.g., it is open to question whether Case No. C-70/95 *Sodemare supra* n. 2, is still good law.

provide services and on free movement of workers, proposes an awkward division of labor between the two.

- It is more, first, as it creates a new set of patients' rights – making it not just a liberalization but also a harmonization directive – and second, because it skews the prospects for widespread prior authorization requirements for cross-border treatment, promoting liberalization.

In sum, the Commission's proposal follows the familiar sequence whereby negative integration – striking down barriers to the market freedoms – breeds the need for positive integration or harmonization, elaborating rights and obligations in legislation that strikes a new balance between private freedoms and legitimate public interests.

If adopted, the proposed directive is bound to act as a catalyst for further change. Wholly appropriately, this change will initially revolve around individual patients' rights. However, it would also be compatible with demand-driven reform of EU healthcare markets that is based on patients' collective interests as consumers, and on the supply side, the dynamics triggered by the proposal are likely to promote the application of the freedom of establishment to healthcare. What are the chances of any of this actually happening? The fate of the Proposed Patients' Rights Directive may still be subject to the vagaries of the EU legislative process, but given that the argument against prior authorization has been forcefully made, it would appear that the genie is already out of the bottle.

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